Virginia Regulatory Town Hall
Agency Background Document
Proposed Regulation

Agency Name: Department of Rehabilitative Services
VAC Number: § 22 VAC 30-40
Regulation Title: Protection of Human Research Participants
Action Title: Human Research Regulations
Date: April 5, 1999

Summary:

A statement explaining the regulation or amendment in a general way using plain and clear language. The summary shall give notice of the substantive provisions contained in a new regulation that is being promulgated or of all changes to an existing regulation that is being amended.

The proposed regulation is necessary for the agency to comply with Section 51.5-5.1 of the Code of Virginia. This law mandates the Department and the Board of Rehabilitative Services promulgate regulations to assure the protection of participants in human research conducted or authorized by the Department, the Woodrow Wilson Rehabilitation Center, and any Employment Services Organization or Center for Independent Living (hereinafter referred to as an "institution(s)").

The proposed regulation establishes the policy (§22 VAC 30-40-40) that no human research may be conducted without the voluntary informed consent of the participant or his legally authorized representative and that the informed consent must be documented in writing and supported by the signature of a witness not involved in the research. Human research is defined as any "systematic investigation which utilizes human participants who may be exposed to physical or psychological injury as a consequence of participation and which departs from the application of established and accepted therapeutic methods appropriate to meet the participant's needs" (§22 VAC 30-40-10). Waiver provisions for voluntary informed consent exists in §22VAC 30-40-100.

Each human research study shall be approved by a research review committee. Each institution may establish its own research review committee, may work with other institutions to establish a single committee, or may use the Department of Rehabilitative Services' established committee. (§22 VAC 30-40-40).

§22 VAC 30-40-50 provides a certification process for institutions seeking to conduct or sponsor human research and the reporting requirements for any violation of the research protocol that leads the research review committee to suspend or terminate the research.

§22 VAC 30-40-50 contains the composition of the research review committee(s), the definition of a committee quorum, and the requirement for the committee(s) and the institution(s) to establish procedures and rules for their operation.

The elements of the committee review is contained in §22 VAC 30-40-70. The elements include consideration to potential benefits and risks and the methodology of the research, the degree of risk for nontherapeutic research, the protection of the rights and welfare of participants, voluntary informed consent, competency of the research investigators, equitable selection criteria for research participants, adherence to other criteria as established by the Board for Rehabilitative Services, and whether appropriate studies in nonhuman systems have been conducted prior to the involvement of human participants. This proposed section also contains a 45 day timeline for consideration of a research proposal by a research review committee, the review notification process, the appeals process, and the reporting requirements.

§22 VAC 30-40-80 provides the criteria by which kinds of research would be exempt from the research review committee review.

§22 VAC 30-40-90 provides an expedited review process for certain kinds of research involving no more than a minimal risk. Under the expedited review process, the committee chairperson and one or more experienced reviewers designated by the chair from among the members of the committee may carry out the review.

The requirements for informed consent are in §22 VAC 30-40-100. This section also provides the requirements for the research review committee to waive the requirements to obtain some or all informed consent.

§ 22 VAC 30-40-110 contains the requirements for the preparation and maintenance of adequate documentation of the research review committee activities, the retention period for these records, and access to the records for inspection and copying by authorized employees or agents of the department at reasonable times and in a reasonable manner.

§22 VAC 30-40-120 requires each research review committee to submit to the governor, the General Assembly, and the commissioner or his designee at least annually a report on the human research projects reviewed and approved by the committee, including any significant deviations from the proposals as approved.

The role of the department, commissioner, and the board is established in §22 VAC 30-40-130. The section requires the commissioner to establish and maintain records of institutional assurances, annual reports, and summary description of research projects to be reviewed by the board; to review communications from committees reporting violations of research protocols which led to suspension or termination of the research to ensure that appropriate steps have been taken for the protection of human research participants and keep the board informed of all reviews of violations of research protocol; and arrange for the printing and dissemination of copies of these regulations.

§22 VAC 30-40-140 provides that nothing in this chapter shall be construed as limiting in any way the rights of participants in research under regulations promulgated by the board in response to §37.1-84.1 of the Code of Virginia.

§22 VAC 30-40-150 provides that human research at institutions which are subject to policies and procedures for the protection of human participants by any agency of the federal government shall be exempt from this chapter. Such institutions must notify the commissioner and the board annually of their compliance with the policies and regulations of federal agencies.

Basis:

A statement identifying the source(s) of the state and/or federal legal authority to promulgate the contemplated regulation, including a description of the scope of the authority provided, the extent to which the authorized rulemaking provisions are mandatory or discretionary , and an indication of the relationship between the cited authority and the specific regulation being proposed. Legal citations should include web site addresses if available for locating the text of the cited authority.

§ 51.5-5.1 of the Code of Virginia provides the statutory authority to the Board of Rehabilitative Services to promulgate regulations for protection of human participants in research to effectuate the provisions of Chapter 5.1 (§ 32.1-162.16 et seq.) of Title 32.1 for human research, as defined in § 32.1-162.16.

Purpose:

A specific rather than conclusory statement setting forth the reasoning by which the agency has determined that the proposed regulation is essential to protect the health, safety or welfare of citizens or for the efficient and economical performance of an important governmental function, including a discussion of the problems the regulation's provisions are intended to solve.

The contemplated regulation will establish protocols to approve research proposals involving customers of the department, Woodrow Wilson Rehabilitation Center, any Employment Services Organizations (sheltered workshops) or Centers for Independent Living as mandated by State and Federal law. These protocols will ensure the adequate safeguards for the rights and welfare of human participants and will ensure that such safeguards are consistent with the federal requirements and state law as described in Section 32.1-162 et. seq. of the Code of Virginia. The contemplated regulation will establish a human research review committee to implement these protocols. Researchers will be required to divulge their research plans to a committee in order to obtain approval for the research. Human participants will be provided with information regarding the action and known consequences of the research. Thus, no participant will be subjected to research against his will.

Substance:

A statement detailing any changes, other than strictly editorial changes, that the proposed regulation will implement, along with citations to the appropriate sections of the regulation, including cross-referenced citations when the proposed regulation is intended to replace an existing regulation.

This is a new regulation.

Issues:

The primary advantages and disadvantages for the public of implementing the new regulatory provisions shall be identified, and the advantages and disadvantages to the agency or the Commonwealth shall be identified.

The advantage of this new regulatory provision is that it will ensure that a protocol is in place for protecting human participants of research studies.

There should be no disadvantage to the public.

This same protocol will also provide guidelines for the persons conducting the research. The regulations will require that the researcher devote more time in attending to the rights, safety and welfare of human subjects. It will require more documentation on the part of the researcher and the agency. The protocol could result in certain investigative studies not being implemented due to concern about possible negative effects on the human participants. Therefore, knowledge that could be gathered from these studies may not be available.

These regulatory protocols provide the agency with more control over the research. There is a guideline to follow to ensure that the rights of customers of the agency are protected. However, ensuring the implementation of these regulations will require the agency to assign additional duties to existing staff.

Alternatives:

A specific rather than conclusory statement describing the process by which the agency has considered less burdensome and less intrusive alternatives for achieving the essential purpose, the alternatives considered, and the reasoning by which the agency has rejected such alternatives.

The statutory requirements mandate the proposed regulatory action. Therefore, the department did not consider alternatives to the regulatory process.

Public Comment:

A summary of public comment received during the NOIRA comment period, along with any agency discussion.

No public comments were received.

Clarity of the Regulation:

A statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

The proposed regulations have been reviewed and edited by research analysts, policy analysts, the Board of Rehabilitative Services, and the Office of the Attorney General. No comments were provided indicating that the proposed regulations were unclear.

Periodic Review:

A schedule setting forth when, no later than three years after the proposed regulation is expected to be effective, the agency will initiate a review and re-evaluation of the regulation to determine if it should be continued, amended, or terminated, and the specific and measurable goals the proposed regulation is intended to achieve.

The agency will initiate a review of the effective regulations in March 2002.

Fiscal Impacts:

A statement identifying anticipated regulatory impacts that includes (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; and (d) the agency's best estimate of the number of such entities that will be affected.

These regulations apply to approximately 87 employment services organizations, 12 centers for independence and 3 satellite offices, and the Woodrow Wilson Rehabilitation Center and its affiliates. There are no other localities, businesses or entities affected by the proposed regulations. The regulations are not expected to affect employment. Any increase in cost to the regulated entities is expected to be nominal.